22 February 2024

Principal Researcher (as per the AHREC application form):	Professor Gillian Gould
Organisation:	Southern Cross University
Via email to the Corresponding Researcher(s):	Gillian.gould@scu.edu.au Isistaquit@scu.edu.au Brian.oldenberg2@baker.edu.au Tom.calma@canberra.edu.au

RE: iSISTAQUIT scale-up in indigenous populations of Australia
AHREC Protocol #: 04-23-1080

Dear Gillian,

Thank you for your response to the issues raised by the Aboriginal Health Research Ethics Committee (AHREC). I am pleased to inform you that the submission was reviewed and approved by AHREC at its meeting held on 22/02/2024.

We wish you well with the study and look forward to receiving your progress reports. Please be advised that, in accordance with the National Statement, AHREC requires researchers to submit reports for monitoring purposes on an annual basis. Regardless of the approval date, AHREC implements a streamlined annual reporting deadline for all studies and requires researchers to submit their annual reports in November. Please be advised that your first annual report is due by 30 November 2024. Please also be advised of the standard conditions of approval below.

Should you need additional information or clarification, please feel free to reach out to the AHREC office at 08 8273 7200 or via email at research@ahcsa.org.au

Sincerely yours,

Lida Shams **|** Manager, Research and Ethics on behalf of AHREC

Standard Conditions

1) The approvals are granted based on the documentation and scope outlined by the researcher at the time of the review. AHREC must be notified of, and, approve, any changes to the study including minor or major changes to the study parameters, personnel updates and extension requests.

2) Where applicable, the onus of following the appropriate procedure for obtaining informed consent and protecting the well-being of a participant lies solely with researcher(s).

3) AHREC approvals are valid for three years from the date of the approval letter unless up to a maximum of 5 year approval timeframe is specifically requested, for example, in case of longitudinal studies and research projects conducted under Centres of Research Excellence. AHREC does not grant approvals on an indefinite basis and requires the submission of an extension request before its approval expires.

4) Studies aiming to involve an Aboriginal organisation, e.g. an Aboriginal Community Controlled Health Service, should adapt a partnership approach and go through a meaningful engagement process evidenced by an in-principle support letter or appropriate agreement.
    a. This letter or agreement should clearly articulate the time, expertise and resources required to support the study.
    b. Study timeframes and tools should be implemented with respect to the characteristics of each context engaged without an adverse impact on the quality of care and capacity of service.
    c. The Committee recognises that this process may not always be possible to finalise ahead of the ethical review process and advises that its approval is conditional upon the consultation process occurring to the satisfaction of the Aboriginal organisations and people whose support is sought to achieve study goals.

5) Where studies are granted approvals on the basis of the need to source ongoing advice from an established Aboriginal governance structure (e.g. Aboriginal advisory group, steering committee) or, where researchers indicated that it will be established, studies should be implemented as such. Should the ongoing monitoring of a study find that the original approval parameters were not adhered to by researchers, AHREC may further deliberate on the continued ethical acceptability of the study.

6) All adverse events to participants or local organisations and communities must be reported to AHREC immediately. These may include any serious or unexpected effect, unforeseen events and information that may invalidate the ethical integrity of the study.

7) Where possible, research participants should be supported for their time attending research activities. Where gift cards or store credits (Compensation) are provided to research participants in compensation for their time and efforts, that Compensation should (wherever practicable) be limited so that they cannot be used to purchase alcohol or tobacco products. Where a researcher has taken reasonable active steps to seek to limit the use of Compensation for alcohol or tobacco products and have been unable to do so, an unrestricted form of Compensation may be used only for participants in areas where restricted Compensation is unavailable. Researchers shall provide details of their efforts to acquire restricted Compensation as part of their annual report to the Aboriginal Health Research Ethics Committee. If the researchers will provide gift cards to incentivise participation, these should be gift cards that cannot be utilised for the purchase of alcohol or tobacco.

8) Research participants should be offered support for transportation to the location where research activities will take place and/or reimbursed for costs incurred e.g. parking, travel costs. This support should ideally be provided to participants up-front.

9) AHREC requires researchers to submit their annual reports every *November*, by the end of the month, throughout the approval timeframe. Final reports can be submitted at any time. Please find the reporting template at: http://ahcsa.org.au/research-overview/ethical-review-ahrec/

10) As part of AHREC's monitoring function and in accordance with the NHMRC Guidelines, where the Committee identifies that a study is high risk due to its interest in issues that are highly sensitive to Aboriginal communities or has become high risk due to its overall code of conduct; it requires researchers to submit their manuscripts for review and approval before publication. The researchers are notified of this advice specifically during the approval timeframe.